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REMARKS

This Amendment C amends the claims as presented in Amendment B, which was submitted with a request for continued examination. Claims 17, 18, 24, 25, 26, 30, 31, 34, and 35 have been amended. New claims 36 to 57 are submitted. Claims 17 to 21; 24 to 31; and 34 to 57 remain in the application. Of these, claims 17, 40, and 46 are independent system claims, and claims 34, 51, and 55 are the dependent method claims.

The applicant thanks the Examiner for his time and attention during a personal interview conducted on September 15, 2004. Claims 17 to 21, 24 to 31, and 34 to 39 were submitted in draft form prior to the interview and were discussed during the interview. The terminology in Claim 17, as presented in this Amendment C, differs somewhat from draft claim 17 as discussed during the interview, in that the terminology used to define the platform region in Claim 17 is now patterned more closely upon the terminology that defines the platform region in method claim 34 (which is dependent upon claim 17), which was discussed at the interview.

As explained during the interview, the independent claims presented in draft form during the interview have been amended to define treatment of a vertebral body as well as to define the second tool as including a platform region that is sized and configured to be disposed relative to the expandable region of the first tool to define an expansion barrier. As further defined in the independent claims, the expansion barrier directs expansion of the expandable body in a desired direction away from the platform region.

During the interview, one of the co-inventors Karen Talmadge described to the Examiner the surprising discovery that unexpected and/or unpredictable variations in local cancellous bone structure, strength, and density occur in vertebral bodies. These unexpected and/or unpredictable variations in cancellous bone can cause an expandable void creation tool to expand in unpredictable ways. A solution to this surprising discovery and attendant result was to impose directionality to the expansion by the use of a platform, as defined in the independent claims, which is disposed relative to the expandable region of the void creation tool, to direct expansion in a desired direction and to prevent expansion towards the platform.

Support for the subject matter defined in the claims can be found, e.g. in Figs. 44 and 45, and in the specification on page 40, line 24 to page 42, line 21. In this portion of the Specification, use of a platform is described in the context of a tibial plateau, and the Specification on page 42,

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beginning on line 12, specifically states that platforms can be used to direct the expansion of expandable bodies in other localized interior bone regions. The Specification identifies a vertebral body as a bone having an interior region (cancellous bone) that can be treated using an expandable body (see, e.g., Figs. 5A to 5Q and the Specification beginning on page 13).

During the interview, it was pointed out to the Examiner that Scholten US 4, 969,888 (the reference applied against previous claims in this case) does not teach or suggest the use of a platform as defined in the claims.

The remainder of the new claims added in this Amendment are directed to the same fundamental technical features discussed during the interview, and therefore are not believed to enlarge the scope of the Examiner's examination of the claims.

More particularly, new independent system claim 40 is patterned upon claim 17, with the first tool being defined as having a "void forming region that enlarges to form a void" instead of an "expandable body sized and configured to form a void." New independent method claim 51 is dependent upon new system claim 40 in the same manner that method claim 34 is dependent upon system claim 17. The new dependent system claims 41, 42, 43, 44, and 45 are patterned upon dependent system claims 26, 30, 31, 38, and 39, respectively. The new dependent method claims 52, 53, and 54 are patterned after dependent method claims 35, 36, and 37, respectively.

New independent system claim 46 is patterned upon claim 17 and 40, with the first tool instead being defined as having a "compacting region that enlarges to form a void." New independent method claim 55 is dependent upon new system claim 46 in the same manner that method claim 34 is dependent upon system claim 17. The new dependent system claims 47, 48, 49, and 50 are patterned upon dependent system claims 30, 31, 38, and 39, respectively. The new dependent method claims 56 and 57 are patterned after dependent method claims 36 and 37, respectively.

Support for the terminology in these claims can be found, e.g., on page 17, lines 17 to 19 and lines 23 to 30.

As also discussed during the interview, the applicant indicated that it would submit with the Amendment a Supplemental Information Disclosure Statement making of record addition documents in view of the new claim language.

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It was also mentioned that there were co-pending, later filed applications assigned to the owner of this application having claims directed to particular platform structures. For the record, these applications are:

- (1) Serial No. 10/001,937 (Applicant Docket No. 17239-FOR)
Filed: October 25, 2001
Pending Before: Examiner A. Ramana
Group Art Unit: 3732
- (2) Serial No. 10/848,514 (Applicant Docket No. 17208-FOR CIP)
Filed: May 18, 2004
Pending Before: Examiner is Not Known
Group Art Unit: 3731
- (3) Serial No. 09/828,470 (Applicant Docket No. 17208-FOR)
Filed: April 6, 2001
Pending Before: Examiner K. Odland
Group Art Unit: 3743
- (4) Serial No. 10/783,723 (Applicant Docket No. 17207-FOR DIV2)
Filed: February 20, 2004
Pending Before: Examiner is Not Known
Group Art Unit: 3763

To the extent that there were not already of record in this case, documents that are of record in these co-pending cases are listed in the Supplemental Information Disclosure Statement submitted herewith. These documents are not believed to teach or suggest the subject matter defined in the amended claims, but are nevertheless being listed in the Supplemental Information Disclosure Statement in interest of full disclosure

Also, additional documents have been brought to the attention of the applicant by a third party in the course of infringement litigation involving Scholten US 5,108,404 and US 4,969,888 (already of record in this case); Reiley et al US 6,235,043 (listed in the Supplemental Information Disclosure Statement and as to which the instant case claims CIP status from the parent application 08/188,224 (Now Abandoned)); and Reiley et al US 6,248,110 (listed in the attached Supplemental Information Disclosure Statement and which issued from the parent application of the instant

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continuation application). These additional documents (listing in the attached Supplemental Information Disclosure Statement) are: US 4,653,489; US 4,369,772; US 4,432,358; US 3,997,138; US 4,772,287; US 3,626,949; US 5,127,912; US 4,987,892; ; and Kunec, J.R., et al., Closed Intramedullary Rodding of Pathologic Fractures with Supplemental Cement, *Clinical Orthopaedics and Related Research*, vol. 188, pp. 183-86 (Sept. 1984). These documents are not believed to teach or suggest the subject matter defined in the amended claims, but are nevertheless being listed in the Supplemental Information Disclosure Statement in interest of full disclosure.

Regarding US 6,248,110 mentioned above, the Examiner's attention is directed to method claim 4 of the '110 Patent, which defines a method for compacting cancellous bone by inserting an expandable body having first and second expandable zones into an interior bone region, one of which expandable regions acts as an expansion barrier for the other expandable region ((this claim is not being asserted in the above-mentioned litigation). Applicant does not believe that the claims pending in this application pose a double patenting issue with respect to claim 4 of the parent '110 Patent, given the differences in scope and substance of the inventions claimed. The claims are not directed to the same invention under 35 U.S.C. § 101 (no statutory double patenting); and there will be no extension of the patent term, as the pending application and the '110 Patent (both owned by the present applicant) claim the benefit of the same priority date and thus share the same 20 year term (*In re Scheller* and non-statutory double patenting are not applicable).

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Applicant believes that the claims, as amended, are in condition for allowance. Allowance of claims 17 to 21; 24 to 31; and 34 to 57 is respectfully requested. If the Examiner believes that questions or matters of clarification remain, which can be handled expeditiously by an interview, either in person or by telephone, to advance prosecution of this case, the applicant remains committed to proceed on that basis.

Respectfully Submitted,

By 
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